

### **REMARKS**

Claims 1-15 are currently pending in this application, of which claims 14 and 15 are currently amended. Claims 10 and 11 were previously deemed allowable, along with claims 4, 7, 9, 12 and 13 if rewritten to overcome the objection for being dependent upon a rejected base claim. Applicants respectfully request favorable consideration of the present application in light of the amendments to the claims and the following remarks.

#### **Claim Rejections – 35 USC § 112**

On page 2 of the Office Action, claims 14 and 15 were rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. In particular, the phrase “into an interior portion thereof” was deemed indefinite based on the term “thereof.” Claims 14 and 15 have been amended to remove the term “thereof” and instead include the following language “into an interior portion of the cylindrically shaped mesh such that the mesh expands radially outwards against the sides of the hole.” Applicants respectfully assert that this amendment particularly points out and distinctly claims the subject matter of the present invention. As such, Applicants respectfully request that this rejection be withdrawn in favor of an indication of allowance.

#### **Claim Rejections – 35 USC 102(e) - Kotula**

Claims 1-3, 5-6, 8 and 14 were rejected under 35 USC 102(e) as being anticipated by US Patent No. 5,846,261 to Kotula et al (“Kotula”). Applicants respectfully traverse this rejection as set forth below.

In order for a reference to anticipate the present claimed invention under 35 U.S.C. 102(e), it must be shown that each and every element of the claim can be found in the reference. If it can be shown that one element of the claim is missing or not met by the cited

reference, the rejection must be withdrawn as inappropriate.

Claim 1, as amended, describes a method of sealing a hole in a body part. The first step involves introducing a generally cylindrical shaped mesh into the hole. The second step involves moving at least one end of the cylindrical shaped mesh at least partially into an interior portion of the cylindrical shaped mesh such that the mesh expands radially outward against sides of the hole.

Claim 14, as amended, describes a method of sealing a hole in a body. The first step involves introducing a generally cylindrically shaped mesh into the hole. The second step involves pushing a proximal end of the cylindrically shaped mesh at least partially into an interior portion of the cylindrical shaped mesh such that the mesh expands radially outward against sides of the hole.

Kotula appears to be silent with regard to at least one element found in amended claims 1 and 14, such that the rejection for anticipation should be withdrawn. Among other voids, Kotula does not disclose the Claim 1 feature of "moving at least one end of the cylindrical shaped mesh at least partially into an interior portion of the cylindrical shaped mesh *such that the mesh expands radially outwards against sides of the hole,*" much less the claim 14 feature of "pushing a proximal end of the cylindrically shaped mesh at least partially into an interior portion of the cylindrical shaped mesh *such that the mesh expands radially outward against sides of the hole.*"

Kotula discloses a device for sealing a septal defect in a human heart. The device is constructed from a memory-shape material (i.e. Nitinol) and includes a generally tubular middle section and enlarged "shoulder" portions on either end of the tubular middle section. The generally tubular middle portion is dimensioned to be positioned within the lumen constituting the septal defect, while the enlarged shoulder portions are dimensioned to

anchor the device in place. In one embodiment, each end of the device is depressed inward towards the center of the lumen of the tubular middle section such that “clamps” 60 attached to the ends are recessed within the device. (*Col. 12, lines 32-36*). That said, it does not appear that the inward movement of the clamps or ends of the Kotula device forces the tubular middle section to expand radially outwards against the side of the septal lumen. This is borne out, among other places, by the fact that the Kotula device is constructed from shape-memory material. That is, the shape-memory characteristics cause the Kotula device to automatically return to its predetermined, original shape (i.e. tubular body portion with opposing enlarge shoulder portions) after being expelled from a delivery catheter. The shoulders form the primary anchoring mechanism for the Kotula device, with one disposed on either side of the septal lumen to maintain the tubular middle portion (and the entire device) in position. It is taught in Kotula that the tubular middle section may be configured to expand into contact with the septal lumen to augment the anchoring features of the shoulders. (*Col. 9, lines 53-65*). However, this radial expansion of the tubular middle section is caused by the shape-memory characteristics of the Kotula device and *not* due to any inward movement of the ends into the interior of the device, as set forth in claims 1 and 14.

Because Kotula fails to teach or disclose at least one claimed feature in the independent claims 1 and 14, Applicants respectfully submit that the rejection under 35 USC 102(e) should be withdrawn in favor of an indication of allowance, which is hereby earnestly solicited. Claims 2-3, 5-6, and 8, being dependent upon and further limiting independent claim 1, should be allowable for the reasons set forth in support of the allowability of claim 1, as well as the additional limitations they contain.

**Claim Rejections - 35 USC 102(e) - Lechinsky**

Claim 15 was rejected under 35 USC 102(e) as being anticipated by US Patent No. 5,904,713 to Leschinsky. Applicants respectfully traverse this rejection as set forth below.

In order for a reference to anticipate the present claimed invention under 35 USC 102(e), it must be shown that each and every element of the claim can be found in the reference. If it can be shown that one element of the claim is missing or not met by the cited reference, the rejection must be withdrawn as inappropriate.

Claim 15, as amended, describes a method of sealing a hole in a body. The first step involves introducing a cylindrically shaped mesh into the hole. The second step involves pulling a distal end of the cylindrically shaped mesh at least partially back into an interior portion of the cylindrical shaped mesh such that the mesh expands radially outwards against sides of the hole.

The Leschinsky reference appears to be silent with regard to at least one element found in amended claim 15, such that rejection for anticipation should be withdrawn. First, contrary to the assertion in the Office Action, the Leschinsky reference does *not* appear to disclose the feature of introducing a *generally cylindrical shaped mesh* into a hole. Rather, Leschinsky discloses the introduction of a pair of "substantially tubular" bodies (*Col. 2, lines 44-48*) connected along a septum (*Col. 3, line 2*), each having a D-shaped cross sectional such that "upon inversion of the second leg the first leg and the second leg together have a substantially round cross section and assume the cross sectional shape of the vessel." (*Col. 3, lines 17-22*). Thus, upon introduction into the body, the device disclosed in Leschinsky is not generally cylindrical, but instead at best is comprised of two half-cylinders, that only take a substantially cylindrical form once the second leg is inverted. This occurs after insertion into the body. This feature is even more apparent when one considers that the two legs are connected by a septum. Because of this connection, at least one side of each tubular object must be flat, and therefore it is *not* generally cylindrical, in contra-distinction to the mesh of the present invention (set forth in claim 15).

Moreover, in similar fashion to the void in Kotula discussed above with respect to claims 1 and 14, Leschinsky also appears to be silent regarding the claim 15 feature of “pulling a distal end of the cylindrically shaped mesh at least partially back into an interior portion of the cylindrical shaped mesh such that the mesh expands radially outwards against sides of the hole.”

In light of the above-identified voids in Leschinsky, Applicants respectfully submit that this reference fails to teach or disclose at least one claimed feature in the independent claim 15. As such, Applicants respectfully submit that the rejection under 35 USC 102(e) should be withdrawn in favor of an indication of allowance, which is hereby earnestly solicited.

**Allowable Subject Matter**

Applicants wish to thank the Examiner for the allowance of claims 10 and 11, and for the indication of allowability with respect to claims 4, 7, 9, 12 and 13.

**CONCLUSION**

The foregoing amendment has been submitted to place the present application in condition for allowance. Favorable consideration and allowance of the claims in this application is respectfully requested. In the event that there are any questions concerning this Amendment or the application in general, the Examiner is cordially invited to telephone the undersigned attorney so that prosecution may be expedited.

Respectfully submitted,  
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